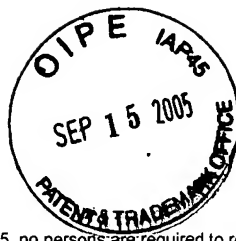


Doc Code: AP.PRE.REQ



PTO/SB/33 (07-05)
Approved for use through xx/xx/200x. OMB 0651-00xx
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

1322.0057CNT

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on _____

Signature _____

Typed or printed
name _____

Application Number

10/759,218

Filed

January 20, 2004

First Named Inventor

Durward I. Faries, Jr.

Art Unit

2859

Examiner

Jagan, M.

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

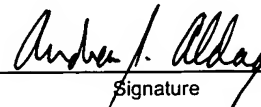
I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒ attorney or agent of record. 40,483
Registration number _____

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____



Signature

Andrew J. Aldag

Typed or printed name

(301) 424-3640

Telephone number

09/15/2005

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



PRE-APPEAL BRIEF REQUEST FOR REVIEW

The following are Applicants' remarks setting forth reasons as to why the Examiner's rejections with respect to independent claims 47, 59, 71 and 72 are improper and without basis and should therefore be withdrawn.

Rejection of claims 71 and 72 as being anticipated by Jordan

The Examiner rejects independent claims 71 and 72 under 35 U.S.C. § 102(a) as being anticipated by U.S. Patent No. 5,875,282 to Jordan et al. ("Jordan"). Each of claims 71 and 72 recites the feature of a temperature sensor assembly being affixed to one of a first panel, a second panel and a base of a medical device, where the temperature sensor assembly directly measures a medical item temperature and visually indicates the measured medical item temperature.

In contrast, Jordan discloses a warmer controller 10 that includes a temperature sensor 80 secured to a base or energy reservoir 88 (see Fig. 4 and Col. 7, lines 12-40 of Jordan), while a visual temperature display 34 is secured to a front face of the warmer controller (see Fig. 1 and Col. 6, lines 30-33 of Jordan). In other words, the temperature sensor 80 and the display 34 of Jordan are secured on two separate panels or surfaces of the controller. Jordan therefore fails to disclose a temperature sensor assembly that directly measures a medical item temperature and visually indicates the measured item temperature and also that is secured to a single wall or panel (i.e., a first panel, a second panel or a base) as recited in claims 71 and 72. This rejection is therefore improper and should be withdrawn, since Jordan fails to disclose every recited feature of each of claims 71 and 72.

Rejection of claims 47 and 59 as being obvious over Kashyap in view of Jordan

The Examiner rejects independent claims 47 and 59 under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 4,336,435 to Kashyap et al. ("Kashyap") in view of Jordan. Claim 47 recites a medical device for visually indicating a temperature of a medical item placed therein including a receptacle defined between first and second panels of the medical device and for receiving the medical item within the receptacle, where the medical device is configured such

U.S. Patent Application No. 10/759,218
Pre-Appeal Brief Request for Review

that any thermal treatment of the medical item received within the receptacle occurs only via heat transfer between the medical item and an external environment surrounding the medical device.

Similarly, claim 59 recites a method of visually indicating a temperature of a medical item placed in a medical device, including the step of receiving the medical item within a receptacle defined between first and second panels of the device, where the medical device is configured such that any thermal treatment of the medical item received within the receptacle occurs only via heat transfer between the medical item and an external environment surrounding the medical device.

Kashyap teaches a microwave apparatus for heating liquid in a container, including a bag holder 8 to support a blood or plasma bag and that is disposed within a cavity 5 of the apparatus (see Figure 2 of Kashyap). The bag holder 8 is mounted to a wall 25 of the apparatus with a rotatable shaft 9 (See Fig. 5 of Kashyap). In one embodiment (Figs. 6 and 7 of Kashyap), a temperature probe 30 is mounted to shaft 9 to contact a medical bag that is supported by the bag holder and heated within the cavity of the apparatus.

In the final office action, the Examiner construes the bag holder 8 as the recited medical device of claims 47 and 59, and further construes at least one of the recited first and second panels of the medical device as the cavity wall 25. The Examiner then construes the microwave apparatus as an external environment surrounding the bag holder in order to assert that Kashyap teaches the recited feature that any thermal treatment of the medical item received within the receptacle occurs only via heat transfer between the medical item and an external environment surrounding the medical device. However, the bag holder (construed by the Examiner as the recited medical device) does not include the cavity wall 25 as asserted by the Examiner. Rather, this cavity wall 25 is a wall of the apparatus (construed by the Examiner as the external environment).

The rationale utilized by the Examiner in an attempt to assert these recited features of claims 47 and 59 are taught by Kashyap is unreasonable and improper, since the medical device of Kashyap is clearly the apparatus itself and not a component of the apparatus (i.e., the bag

U.S. Patent Application No. 10/759,218
Pre-Appeal Brief Request for Review

holder). Further, the Examiner cannot reasonably construe the bag holder as the recited medical device and, in the same instance, assert that a cavity wall of the microwave apparatus is part of the bag holder. Accordingly, the rejection of these claims based upon Kashyap in view of Jordan should be withdrawn.

Rejection of claims 47 and 59 as being obvious over Smith in view of Suzuki

The Examiner rejected independent claims 47 and 59 under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 4,994,021 to Smith et al. ("Smith") in view of U.S. Patent No. 4,859,360 to Suzuki et al. ("Suzuki"). In addition to the recited features noted above for claims 47 and 59, claim 47 recites that the medical device includes a temperature sensor assembly to directly measure a medical item temperature and visually indicate the measured medical item temperature. Claim 59 further recites a method of visually indicating a temperature of a medical item placed in a medical device, including the further step of directly measuring a medical item temperature and providing a visual indication of the measured medical item temperature via a temperature sensor assembly.

Smith teaches an apparatus for collecting and freezing blood plasma that includes a form 60 having a cover portion 62 hinged to a back portion 66 (Figs. 3 to 3C of Smith). The form 60 receives one or more plasma bags 16 and presses them into a wedge or V-shape so that the bags can be frozen in this shape (see Fig. 5 and Col. 5, line 60 to Col. 6, line 26 of Smith).

The Examiner acknowledges that Smith fails to teach any temperature sensor assembly that measures and provides a visual indication of a medical item temperature. However, the Examiner cites Suzuki for its teaching of providing a temperature indicator to a container such as a conventional medical blood bag. From this, the Examiner asserts that it would have been obvious to modify Smith to include a temperature sensor assembly with the recited features of claims 47 and 59.

However, there is no motivation for providing such a feature in Smith, since Smith is only concerned with freezing blood or plasma bags into a wedge configuration. The Examiner has provided no reason as to why one would be motivated to monitor the temperature of a blood

U.S. Patent Application No. 10/759,218
Pre-Appeal Brief Request for Review

or plasma bag that is being frozen (i.e., not used for infusion into a patient) in the apparatus of Smith.

Further, even assuming that one would be motivated to provide such a feature to the plasma bags 16 of Smith, this would still not meet the feature of claim 47 of providing the medical device (i.e., not the plasma bag) with a temperature sensor assembly. In addition, the feature of claim 59 of providing a visual indication of the medical item temperature would not be met, since the plasma bag would be disposed within the form 60 of Smith and, therefore, the temperature indicator on the plasma bag of Smith could not be read absent some modification to the form 60. Therefore, the rejection of claims 47 and 59 based upon Smith in view of Suzuki is unreasonable and improper and should be withdrawn.

Rejection of claims 71 and 72 as being obvious over Ginsburg in view of Jordan

The Examiner rejected independent claims 71 and 72 under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,989,238 to Ginsburg in view of Jordan.

As noted above, each of claims 71 and 72 recites the feature of a temperature sensor assembly being affixed to one of a first panel, a second panel and a base of a medical device, where the temperature sensor assembly directly measures a medical item temperature and visually indicates the measured medical item temperature.

Ginsburg teaches an infusion system 10 including a chamber 28 to receive a bag or reservoir 30 of fluid, a thermistor 34 in contact with the reservoir 30 to monitor the temperature of fluid within the reservoir, and a screen 24 to provide information about the set points for volume, infusion rate and temperature of the fluid. As can clearly be seen from Figs. 1 and 2 of Ginsburg, the thermistor 34 and the screen 24 are on different panels or surfaces of the system housing. In addition, as acknowledged by the Examiner, Ginsburg fails to teach an assembly for visually indicating a measured temperature of the fluid reservoir.

However, the Examiner relies upon Jordan (discussed above) to assert that it would have been obvious to provide such a feature to Ginsburg. Even assuming this is true, the combination would still fail to meet every recited limitation of claims 71 and 72, since both Ginsburg and

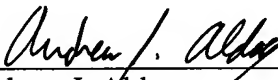
U.S. Patent Application No. 10/759,218
Pre-Appeal Brief Request for Review

Jordan fail to teach a temperature sensor assembly that directly measures a medical item temperature and visually indicates the measured item temperature and that is also secured to a single wall or panel (i.e., a first panel, a second panel or a base) as recited in these claims. This rejection of claims 71 and 72 is therefore improper and should be withdrawn.

Since the remaining claims 48-58 and 60-70 depend from one of independent claims 47 and 59, these claims should also be allowed based upon the previous remarks for their parent claims.

In view of the foregoing, Applicants request a favorable review of the application, withdrawal of all of the outstanding rejections and allowance of the application.

Respectfully submitted,



Andrew J. Aldag
Registration No. 40,483

EDELL, SHAPIRO & FINNAN, LLC
1901 Research Boulevard, Suite 400
Rockville, Maryland 20850-3164
(301) 424-3640
Hand Delivered on: September 15, 2005